

In the Claims

1. (Currently Amended) A composition for administering a cyclosporin compound, the composition comprising:

(a) a dispersible concentrate characterized by being capable of forming, upon contact with an aqueous solution, particles of a size of less than about 100 nm, said dispersible concentrate comprising:

(i) at least one surfactant; and

(ii) an amphiphilic solvent comprising ~~an hydrophilic amphiphilic solvent characterized by being a~~ lower alkyl hydroxy alkanoic acid ester ~~of hydroxyalkanoic acid or an a lower alkyl ester of N-alkyl pyrrolidone~~; and

(b) a pharmaceutically effective amount of the cyclosporin compound.

2. Cancelled

3. (Currently Amended) The composition of claim 21, wherein said lower alkyl hydroxy alkanoic acid ester includes ethyl lactate.

4. Cancelled

5. (Currently Amended) The composition of claim 41, wherein said amphiphilic solvent ~~lower alkyl N-alkyl pyrrolidone~~ includes N-methyl pyrrolidone.

6. (Currently Amended) The composition of claim 1, wherein said ~~hydrophilic amphiphilic~~ solvent includes a combination of a lower alkyl ester of N-alkyl pyrrolidone and a lower alkyl hydroxy alkanolic acid ester.

7. (Currently Amended) The composition of claim 1, wherein said at least one surfactant is a combination of at least two surfactants, at least one surfactant of said combination being a ~~high HLB(hydrophilic/lipophilic balance)~~ hydrophilic surfactant ~~having an HLB of at least about 8~~ and at least one surfactant of said combination being a ~~low HLB having an HLB of less than about 5~~ hydrophobic surfactant.

8. (Original) The composition of claim 7, wherein said combination is a combination of polyoxyethylene(20)sorbitan monolaurate and sorbitan monooleate.

9. (Original) The composition of claim 7, further comprising:
(c) an ethoxylated fat.

10. (Original) The composition of claim 9, wherein said ethoxylated fat is selected from the group consisting of polyethyleneglycol-hydrogenated castor oils.

11. (Currently Amended) The composition of claim 10, wherein said polyethyleneglycol- hydrogenated castor oil is selected from the group consisting of ~~Cremophor EL, Cremophor RH 40 and Cremophor RH 60~~ polyoxyl 35 castor oil, polyoxyl 40 hydrogenated castor oil, and polyoxyl 60 hydrogenated castor oil.

12. (Original) The composition of claim 9, further comprising:

(d) a phospholipid.

13. (Currently Amended) The composition of claim 12, wherein said phospholipid is selected from the group consisting of egg phospholipid, bovine heart phospholipid, and soy phospholipid.

14. (Original) The composition of claim 12, further comprising:

(e) a fatty acid ester.

15. (Original) The composition of claim 14, wherein said fatty acid ester is a solid fat at room temperature.

16. (Original) The composition of claim 15, wherein said fatty acid ester is tricaprin.

17. (Original) The composition of claim 1, wherein said particle size is less than about 60 nm.

18. (Original) The composition of claim 17, wherein said particle size is in a range of from about 5 nm to about 50 nm.

19. (Original) The composition of claim 1, wherein the cyclosporin compound is Ciclosporin.

20. (Original) A composition for administering a cyclosporin compound, the composition comprising a pharmaceutically effective amount of the composition of claim 1 and an aqueous solution as a diluent for said pharmaceutically effective amount of the composition of claim 1.

21. (Original) A composition for administering a cyclosporin compound, the composition comprising a lyophilized composition, said lyophilized composition being formed from a pharmaceutically effective amount of the composition of claim 1 and an aqueous solution as a diluent for said pharmaceutically effective amount of the composition of claim 1 to form a diluted solution. said diluted solution being lyophilized to form said lyophilized composition.

22. (Currently Amended) A method for administering a cyclosporin compound to a subject in need of treatment thereof, the method comprising the step of administering a pharmaceutically effective amount of the composition of claim 1 to the subject.

23. (Original) The method of claim 22, wherein said pharmaceutically effective amount of the composition of claim 1 is administered to the subject through oral administration.

24. (Original) The method of claim 23, wherein said pharmaceutically effective amount of the composition of claim 1 is administered as a dispersion with an aqueous solution as a diluent.

25. (Original) A method for determining storage stability of a formulation containing a cyclosporin compound, the method comprising the step of analyzing the composition of claim 1 for particle size, such that if said particle size is less than about 100 nm, the formulation is determined to be stable.

26. (Currently Amended) A composition for administering a cyclosporin compound, the composition comprising:

(a) a dispersible concentrate characterized by being capable of forming, upon contact with an aqueous solution, particles of a size of less than about 100 nm, said dispersible concentrate comprising:

(i) an ethoxylated fat; and

(ii) an hydrophilic amphiphilic solvent characterized by being comprising a lower alkyl hydroxy alkanoic acid ester or a lower alkyl ester of hydroxyalkanoic acid or an N-alkyl pyrrolidone; and

(b) a pharmaceutically effective amount of the cyclosporin compound.

27. (Original) The composition of claim 26, wherein said ethoxylated fat is selected from the group consisting of polyethyleneglycol-hydrogenated castor oils.

28. (Currently Amended) The composition of claim 27, wherein said ethoxylated fat is selected from the group consisting of ~~Cremophor EL, Cremophor RH 40 and Cremophor RH 60~~ polyoxyl 35 castor oil, polyoxyl 40 hydrogenated castor oil, and polyoxyl 60 hydrogenated castor oil.

29. (Currently Amended) The composition of claim 26, wherein said ~~hydrophilic~~ amphiphilic solvent includes a lower alkyl hydroxy alkanoic acid ester.

30. (Currently Amended) The composition of claim ~~29, 26,~~ wherein said ~~lower alkyl hydroxy alkanoic acid ester~~ amphiphilic solvent includes ethyl lactate.

31. (Currently Amended) The composition of claim 26, wherein said ~~hydrophilic~~ amphiphilic solvent includes a lower alkyl ester of N-alkyl pyrrolidone.

32. (Currently Amended) The composition of claim 31, wherein said lower alkyl ester of N-alkyl pyrrolidone includes N-methyl pyrrolidone.

33. (Currently Amended) The composition of claim 26, wherein said ~~hydrophilic~~ amphiphilic solvent includes a combination of a lower alkyl ester of N-alkyl pyrrolidone and a lower alkyl hydroxy alkanoic acid ester.

34. (New) The composition of claim 7, wherein said hydrophilic surfactant has an HLB (hydrophilic/lipophilic balance) of at least 8.

35. (New) The composition of claim 7, wherein said hydrophobic surfactant has an HLB of less than 5.

36. (New) The composition of claim 7, wherein said hydrophobic surfactant comprises a sorbitan fatty acid ester.

37. (New) The composition of claim 7, wherein said hydrophobic surfactant comprises PEG-6 glyceryl monooleate.

38. (New) The composition of claim 7, wherein said hydrophobic surfactant comprises propylene glycol laurate.

39. (New) The composition of claim 7, wherein said hydrophilic surfactant comprises polyoxyethylene-sorbitan-fatty acid ester.

40. (New) The composition of claim 7, wherein said hydrophilic surfactant comprises sucrose fatty acid ester.

41. (New) The composition of claim 12, wherein said phospholipid comprises lecithin.

42. (New) The composition of claim 1, further comprising amphiphilic solvent selected from the group consisting of ethylene glycol, glycofurol and PEG 400.

43. (New) The method of claim 22, wherein said subject is in need of treatment of a condition selected from the group consisting of autoimmune disease and inflammatory conditions.

44. (New) The method of claim 22, wherein said subject is in need of treatment of organ or tissue transplant rejection.

45. (New) The method of claim 22, wherein said pharmaceutically effective amount of the composition of claim 1 is administered to the subject through topical administration.

46. (New) The method of claim 22, wherein said pharmaceutically effective amount of the composition of claim 1 is administered to the subject through parenteral administration.

47. (New) The method of claim 22, wherein said pharmaceutically effective amount of the composition of claim 1 is administered as a capsule.

48. (New) The method of claim 22, wherein said pharmaceutically effective amount of the composition of claim 1 is administered as a tablet.

49. (New) The method of claim 22, wherein said pharmaceutically effective amount of the composition of claim 1 is administered as a powder.

50. (New) A method for administering a cyclosporin compound to a subject in need thereof, the method comprising the step of administering a pharmaceutically effective amount of a composition, said composition comprising a dispersible concentrate characterized by being capable of forming, upon contact with an aqueous solution, particles of a size of less than about 100 nm, said dispersible concentrate comprising at least one surfactant and an amphiphilic solvent comprising a lower alkyl hydroxy alkanoic acid ester or a lower alkyl ester of N-alkyl pyrrolidone.

51. (New) A composition for administering a cyclosporin compound, the composition comprising:

(a) a dispersible concentrate characterized by being capable of forming, upon contact with an aqueous solution, a solid particulate suspension containing the cyclosporin compound, said particulate suspension containing particles of a size of less than about 100 nm, said dispersible concentrate comprising:

- (i) at least one surfactant; and
 - (ii) an amphiphilic solvent comprising a lower alkyl hydroxy alkanoic acid ester or a lower alkyl ester of N-alkyl pyrrolidone; and
- (b) a pharmaceutically effective amount of the cyclosporin compound.